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Remarks:

Regarding the rejection of claims 25 and 26 under 35 USC 112, 2nd paragraph:

The presently amended claims are believed to address and overcome the Examiner's rejection of claims 25 and 26. Accordingly, withdrawal of the rejection is solicited.

Regarding the rejection of claims 1-8, and 13-26 under 35 USC 102(e) or 35 USC 103(a) in view of US 6080387 to Zhou, et al. (hereinafter "Zhou"):

The applicant traverses the rejection of the claims in view of the reference to Zhou, particularly in view of the foregoing amendments to the claims.

The applicant points out that in the presently amended claims 1, 25, 26 - 28 provided in this paper each of the aforesaid includes a new limitations which highlights that the "systems" according to the invention which include (i) the selected alcohol(s), (ii) the pH adjusting agent(s) (when present) and (iii) water, at the recited pH levels and wherein the (i) and (iii) are in the recited proportions, themselves provide a "...at least 1 log₁₀ of Poliovirus reduction in the absence of further constituents..", e.g., further optional constituents, viz:

 "...an alcohol constituent selected from the group consisting of methanol, ethanol, n-propanol, isopropanol, n-butanol, benzyl alcohol, and mixtures thereof which is present in an amount of from about 40 and 70 weight percent;

 an effective amount of a pH adjusting agent such that the pH range of the composition is from about 7.0 to about 13.0;

 and water, to 100 weight percent;

 which aforesaid alcohol, pH adjusting agent and water ~~alkaline aqueous alcohol constituents~~ are sufficient to provide at least 1 log₁₀ of Poliovirus reduction in the absence of further constituents; ..."

This feature is not known, nor demonstrated, nor would be obvious from the prior art.

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The Examiner is respectfully reminded that to anticipate a claim under 35 USC §102, the reference must teach each and every element of the claim. See MPEP 2131. "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). "The identical invention must be shown in as complete detail as is contained in the ... claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).

With respect to a finding of "obviousness" the Examiner is respectfully reminded that the determination of obviousness under § 103(a) requires consideration of the factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1 [148 USPQ 459] (1966): (1) the scope and content of the prior art; (2) the differences between the claims and the prior art; (3) the level of ordinary skill in the pertinent art; and (4) secondary considerations, if any, of nonobviousness. *McNeil-PPC, Inc. v. L. Perrigo Co.*, 337 F.3d 1362, 1368, 67 USPQ2d 1649, 1653 (Fed. Cir. 2003). There must be some suggestion, teaching, or motivation arising from what the prior art would have taught a person of ordinary skill in the field of the invention to make the proposed changes to the reference. *In re Fine*, 837 F.2d 1071, 1075, 5 USPQ2d 1596, 1600 (Fed. Cir. 1988). But see also *KSR International Co. v. Teleflex Inc.*, 82 USPQ2D 1385 (U.S. 2007).

A methodology for the analysis of obviousness was set out in *In re Kotzab*, 217 F.3d 1365, 1369-70, 55 USPQ2d 1313, 1316-17 (Fed. Cir. 2000) A critical step in analyzing the patentability of claims pursuant to section 103(a) is casting the mind back to the time of invention, to consider the thinking of one of ordinary skill in the art, guided only by the prior art references and the then-accepted wisdom in the field. Close adherence to this methodology is especially important in cases where the very ease with which the invention can be understood may prompt one "to fall victim to the insidious effect of a hindsight syndrome wherein that which only the invention taught is used against its teacher."

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It must also be shown that one having ordinary skill in the art would reasonably have expected any proposed changes to a prior art reference would have been successful.

Amgen, Inc. v. Chugai Pharmaceutical Co., 927 F.2d 1200, 1207, 18 USPQ2d 1016, 1022 (Fed. Cir. 1991); *In re O'Farrell*, 853 F.2d 894, 903-04, 7 USPQ2d 1673, 1681 (Fed. Cir. 1988); *In re Clinton*, 527 F.2d 1226, 1228, 188 USPQ 365, 367 (CCPA 1976). "Both the suggestion and the expectation of success must be founded in the prior art, not in the applicant's disclosure." *In re Dow Chem. Co.*, 837 F.2d 469, 473, 5 USPQ2d 1529, 1531 (Fed. Cir. 1988).

With regard to Zhou, the applicant again points out that Zhou's compositions necessarily comprise the following constituents (see Zhou, col. 3):

The aerosol formulation comprises an antimicrobial composition that is mixed with a propellant. The composition has the following ingredients: 15

- (a) an anionic polymer or prepolymer,
- (b) a quaternary ammonium compound, the components (a) and (b) combining to form an antimicrobially effective complex; 20
- (c) at least one water-soluble or dispersible organic solvent having a vapor pressure of at least 0.001 mm Hg at 25° C., said at least one organic solvent present in a solubilizing—or dispersion—effective amount;
- (d) an effective amount of a propellant; and 25
- (e) the remainder, water.

Additional adjuncts in small amounts such as buffers, fragrances, dyes and the like can be included to provide desirable attributes of such adjuncts.

Therein is clearly indicated that amongst essential constituents are (a) and (b) which "the components combining to form an antimicrobially effective complex.." This is further supported by Zhou in his statement at column 4 wherein he indicates that:

The antimicrobial composition is preferably prepared by mixing effective amounts of the anionic component and the quaternary ammonium compound in water with agitation. A water miscible solvent and/or dispersing/emulsifying/wetting agent is preferably added before the two main

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As well as at column 5 where he indicates that:

part of the invention. The most preferred range of 5:1 to 1:5 appears to result in an aesthetically pleasing film which has 15 excellent residual antimicrobial efficacy, as well as disinfectancy. This also seems to imply that, in the cured film/residue, there may actually not be complete ion pairing between the quaternary ammonium compound and the anionic sites in the anionic polymer, since the quaternary 20 ammonium active sites are available for residual microbial kill, although there is clearly an interaction between the two components. Again, the mechanism of the film/residue is not

And later at column 5 Zhou unequivocally "critically" identifies the role of the quaternary ammonium compound, or surfactant as being the sole agent responsible for providing a bacteriostatic/disinfectant benefit wherein he recites:

A critical second component of the invention is a quaternary ammonium compound, or surfactant. These types of 40 surfactants are typically used in bathroom cleaners because they are generally considered "broad spectrum" antimicrobial compounds, having efficacy against both gram positive (e.g., Staphylococcus sp.) and gram negative (e.g., Escherichia coli or Klebsiella sp.) microorganisms. Thus, the qua- 45 ternary ammonium surfactant, or compounds, are incorporated for bacteriostatic/disinfectant purposes and should be present in amounts effective for such purposes.

From the foregoing, it is made unequivocally clear that Zhou's compositions require this "(a)+(b) complex" in order to provide an antimicrobial benefit, and particularly in view of the foregoing passages of Zhou, that the quaternary ammonium compound provides the antimicrobial benefit. Thus it is clear to see that the both (a) and (b), (..but especially the quaternary ammonium compound..) are (i) essential constituents, and (ii) the quaternary ammonium compound provides the antimicrobial benefit. Thus the (a)+(b) complex define the operative mechanism for providing an antimicrobial benefit according to Zhou.

In contrast to the above, by even a simple review of the present applicant's specification, applicant's claimed compositions do not require either (a) or (b), nor the "(a)+(b) complex" in order to provide an antimicrobial benefit. Thus, *prima facie*, applicant's

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invention which provides effective antimicrobial efficacy absent the “(a)+(b) complex” is a clear indication that a different operative mechanism is at work, and thus is *prima facie* both unanticipated and nonobvious over the Zhou reference. (For example, applicant’s Ex. 30 demonstrates a 6 log₁₀ reduction of Poliovirus absent both of Zhou’s (a) and or (b), and none of applicant’s examples illustrate Zhou’s (b) polymers). The Examiner’s assertions to the contrary are unsupported by the Zhou reference for the reasons outlined above. The Examiner is further reminded that “A reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant.” *In re Gurley*, 27 F.3d 551, 553 [31 USPQ2d 1130] (Fed. Cir. 1994). Additionally, a reference may teach away from a use when that use would render the result inoperable. *McGinley v. Franklin Sports, Inc.*, 262 F.3d 1339, 1354 [60 USPQ2d 1001] (Fed. Cir. 2001). Thus, it is unequivocally clear that Zhou’s “(a)+(b) complex” are a fundamental and necessary feature of Zhou’s compositions. To follow the Examiner’s line of reasoning in eliminating Zhou’s necessary “(b)” constituent, would effectually render Zhou’s compositions, which rely upon his “(a)+(b) complex” as being inoperable.

In the alternative, at best, the Examiner’s selective reading of Zhou appears to be an impermissible “hindsight reconstruction” of the applicant’s claimed invention. The Examiner is reminded that in *In re Fritch*, 972 F.2d 1260, 1266, 23 USPQ2d 1780, 1784 (Fed. Cir. 1992), the Federal Circuit stated:

“It is impermissible to use the claimed invention as an instruction manual or “template” to piece together the teachings of the prior art so that the claimed invention is rendered obvious. *In re Gorman*, 933 F.2d 982, 987, 18 USPQ2d 1885, 1888 (Fed. Cir. 1991). This court has previously stated that “[o]ne cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention.” (quoting *In re Fine*, 837 F.2d at 1075, 5 USPQ2d at 1600)

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See also *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 220 USPQ 303 (CAFC, 1983); *In re Mercier* 185 USPQ 774, 778 (CCPA, 1975); *In re Geiger* 2 USPQ2d 1276 (CAFC, 1987).

As noted above, in this paper the applicant has amended the independent claims present in the application, as well as added new claims, which are believed to patentably distinguish over the Zhou reference. The amended independent claims include a limitation which recognizes that applicant's compositions are effective in providing excellent efficacy against Poliovirus utilizing a system, viz., an aqueous-alcohol mixture having both one or more alcohol(s) in a specific weight proportion with water in a specific weight proportion, the said aqueous-alcohol mixture being within a specific pH range, and that such system is sufficient to provide effective control of Poliovirus. Support for this new limitation may be found in applicant's specification, inter alia, at Fig. 1 of applicant's specification and the related description in applicant's specification. The attention of the Examiner is directed to applicant's Tables 1, 2, 3A, 3B, 4 and 6C which demonstrate such systems. Applicant's claimed system of aqueous-alcohol mixture within a specific pH range is not demonstrated providing a specific reduction of the Polio virus is not anticipated, nor even remotely suggested by Zhou's very different system which necessarily comprises Zhou's two essential constituents, here his "a) anionic polymer or prepolymer" and b) quaternary ammonium surfactant, both of which are necessary to form Zhou's polymer complex which is used to provide his antipathogenic benefits. Further, as it is also clear that the applicant's invention and its success in the eradication of undesirable pathogens and fungi are based on a system of constituents which are distinguishable from Zhou's "(a)+(b)" combination, applicant's currently claimed compositions should also be considered nonobvious thereover.

Accordingly, in view of the foregoing remarks, reconsideration of the propriety of the rejection under 35 USC 102(e) and/or 35 USC 103(a) is requested, and withdrawal of the rejection is urged.

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Regarding the rejection of claims 1-8, and 13-27 under 35 USC 102(b) and/or 35 USC 103(a) in view of US 3282776 to Kitzke (hereinafter simply "Kitzke"):

The applicant respectfully traverses the Examiner's rejection of the claims as being "anticipated" or "obvious" in view of the Kitzke reference.

Prior to discussing the relative merits of the Examiner's rejection, Applicant points out that unpatentability based on "anticipation" type rejection under 35 USC 102(b) requires that the invention is not in fact new. See *Hoover Group, Inc. v. Custom Metalcraft, Inc.*, 66 F.3d 299, 302, 36 USPQ2d 1101, 1103 (Fed. Cir. 1995) ("lack of novelty (often called 'anticipation') requires that the same invention, including each element and limitation of the claims, was known or used by others before it was invented by the patentee"). Anticipation requires that a *single reference* [emphasis added] describe the claimed invention with sufficient precision and detail to establish that the subject matter existed in the prior art. See, *In re Spada*, 911 F.2d 705, 708, 15 USPQ2d 1655, 1657 (Fed. Cir. 1990).

The principle of "inherency," in the law of anticipation, requires that any information missing from the reference would nonetheless be known to be present in the subject matter of the reference, when viewed by persons experienced in the field of the invention. However, "anticipation by inherent disclosure is appropriate only when the reference discloses prior art that must necessarily include the unstated limitation, [or the reference] cannot inherently anticipate the claims." *Transclean Corp. v. Bridgewood Servs., Inc.*, 290 F.3d 1364, 1373 [62 USPQ2d 1865] (Fed. Cir. 2002); *Hitzeman v. Rutter*, 243 F.3d 1345, 1355 [58 USPQ2d 1161] (Fed. Cir. 2001) ("consistent with the law of anticipation, an inherent property must necessarily be present in the invention described by the count, and it must be so recognized by persons of ordinary skill in the art"); *In re Robertson*, 169 F.3d 743, 745 [49 USPQ2d 1949] (Fed. Cir. 1999) (that a feature in the prior art reference "could" operate as claimed does not establish inherency).

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Thus when a claim limitation is not explicitly set forth in a reference, evidence "must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill." *Continental Can Co.*, 948 F.2d at 1268. It is not sufficient if a material element or limitation is "merely probably or possibly present" in the prior art. *Trintec Indus., Inc. v. Top-U.S.A. Corp.*, 295 F.3d 1292, 1295 [63 USPQ2d 1597] (Fed. Cir. 2002). See also, *W.L. Gore v. Garlock, Inc.*, 721 F.2d at 1554 (Fed. Cir. 1983) (anticipation "cannot be predicated on mere conjecture respecting the characteristics of products that might result from the practice of processes disclosed in references"); *In re Oelrich*, 666 F.2d 578, 581 [212 USPQ 323] (CCPA 1982) (to anticipate, the asserted inherent function must be present in the prior art).

The undersigned also reminds the Examiner that the determination of obviousness under § 103(a) requires consideration of the factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1 [148 USPQ 459] (1966): (1) the scope and content of the prior art; (2) the differences between the claims and the prior art; (3) the level of ordinary skill in the pertinent art; and (4) secondary considerations, if any, of nonobviousness. *McNeil-PPC, Inc. v. L. Perrigo Co.*, 337 F.3d 1362, 1368, 67 USPQ2d 1649, 1653 (Fed. Cir. 2003). There must be some suggestion, teaching, or motivation arising from what the prior art would have taught a person of ordinary skill in the field of the invention to make the proposed changes to the reference. *In re Fine*, 837 F.2d 1071, 1075, 5 USPQ2d 1596, 1600 (Fed. Cir. 1988). But see also *KSR International Co. v. Teleflex Inc.*, 82 USPQ2D 1385 (U.S. 2007).

The Examiner is directed to the presently amended claims presented in this paper.

Turning now to Kitzke, a reading of that prior art document quickly teaches the reader that the component of Kitzke's composition which provides disinfection is the necessary "Quaternary" compounds. Kitzke recites at col. 7:

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(d) *Quaternary*.—Although a vast array of germicides are available commercially today including numerous quaternary compounds the compositions of the invention are limited to a specific class of quaternary compounds described in detail below. These compounds are unexpectedly well suited for use in the surface disinfecting-air sanitizing compositions of the invention by reason of their preeminent bactericidal properties. These quaternaries have been found to provide unobvious and unexpected surface disinfecting and air sanitizing performance when used in the compositions of the invention. 10 15

The need for the quaternary surfactants are reinforced by a review of the results reported on Kitzke's "Table 1" and "Table 3" each of which clearly identify the need for a pair of quaternary ammonium compounds needed to provide a disinfecting benefit to Kitzke's aerosol compositions. Thus, from the foregoing it is clear that Kitzke neither "anticipates" the applicant's currently claimed compositions, or that applicant's currently claimed compositions could be considered "obvious" from the Kitzke reference and especially the compositions taught therein. Kitzke unequivocally teaches his pair of quaternary ammonium compounds as an essential constituent in order to provide a disinfecting benefit, the current applicant's teach a different system which provides as surprisingly effective benefit in controlling unwanted microorganisms. As noted above, and as is presently included in the presently amended claims 1, 25, 26 - 28 provided in this paper, the applicants' invention provides a "system" which include (i) the selected alcohol(s), (ii) the pH adjusting agent(s) (when present) and (iii) water, at the recited pH levels and wherein the (i) and (iii) are in the recited proportions, themselves provide a "...at least 1 log₁₀ of Poliovirus reduction in the absence of further constituents..", e.g., further optional constituents, viz:

"...an alcohol constituent selected from the group consisting of methanol, ethanol, n-propanol, isopropanol, n-butanol, benzyl alcohol, and mixtures thereof which is present in an amount of from about 40 and 70 weight percent;

an effective amount of a pH adjusting agent such that the pH range of the composition is from about 7.0 to about 13.0;

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and water, to 100 weight percent;
 which aforesaid alcohol, pH adjusting agent and water ~~alkaline aqueous~~
~~alcohol constituents~~ are sufficient to provide at least 1 log₁₀ of Poliovirus
 reduction in the absence of further constituents; ...”

This feature is not known, nor demonstrated, nor would be obvious from Kitzke. In view of the foregoing amendments to the claims and remarks presented, withdrawal of all grounds of rejection and allowance of the claims to grant is requested.

Regarding the rejection of claim 28 in view of 35 USC 103(a) in view of US 4695453 to Tuominen, et al. (hereinafter “Tuominen”), in view of US 6080387 to Zhou et al. (“Zhou”) or in view of US 3282776 to Kitzke (“Kitzke”):

The applicants respectfully traverse the Examiner’s rejection of claim 28 in view of Tuominen in view of Zhou, or in view of Tuominen in view of Kitzke.

Tuominen is solely directed to thickened alcohol containing compositions, as summarized by Tuominen at col. 3 which reads:

SUMMARY OF THE INVENTION

This invention relates to alcoholic antibacterial compositions containing a thickening amount of a polymer having the recurring structural unit:



wherein R is a divalent hydrocarbon group and M is a hydrogen atom or an ammonium group. This invention also relates to methods of thickening an alcoholic antibacterial composition and to the use of the thickened alcoholic antibacterial composition as an antibacterial agent.

The above recited polymer combined with an “Alcoholic Antibacterial Composition (AAC)” which comprises a major proportion of C₁-C₈ aliphatic alkanols as well as

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aromatic substituted alkanols, e.g., benzyl alcohol. (Tuominen, col. 2, lines 4 – 14) but preferably the aqueous-alcohol comprises:

- 15 The preferred alcoholic antibacterial compositions preferably contain as active ingredients, a major portion (e.g. between about 40% and about 50% by weight) ethanol (wherein the ethanol contains 4% water), a minor portion (e.g. between about 20% and 30% by
20 weight) anhydrous isopropanol, and a nominal amount (e.g. about 0.5% to about 2% by weight) benzyl alcohol.

As noted at col. 2 of Tuominen. Water forms, at best, only a minor amount of the (AAC), as can be understood from the following excerpt from col. 4:

Alcoholic Antibacterial Composition (AAC): A mixture comprised of approximately 46% by weight ethanol (which contains about 4% water and has been denatured), 27% anhydrous isopropanol, 1% benzyl alcohol and balance water, which is available from Henkel KGaA as Spitacid®.

The polymeric thickener of Tuominen is an essential constituent in all of his compositions. Tuominen fails to indicate the pH of his compositions, and very importantly fails to indicate or demonstrate any efficacy of his compositions against any specific microorganisms.

For the sake of brevity, applicants herein repeat and incorporate by reference the prior remarks made with respect to Zhou as being equally applicable to the current rejection in conjunction with Tuominen. However, the additional consideration of Zhou with Tuominen would not be technically feasible and would be considered inoperable as Tuominen's thickened AAC compositions would be recognized by a skilled artisan as being unsuitable for use in a pressurized, propellant containing composition which is an essential feature of Zhou's compositions as such would be expected to clog any nozzle or dispenser due to the high viscosity of Tuominen's thickened AAC compositions. Such an inoperative combination would not render the applicant's presently claimed invention as being anticipated or being obvious and does not provide a suitable basis for maintaining

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the rejection of the claim. A reference may teach away from a use when that use would render the result inoperable. *McGinley v. Franklin Sports, Inc.*, 262 F.3d 1339, 1354 [60 USPQ2d 1001] (Fed. Cir. 2001). "A reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant." *In re Gurley*, 27 F.3d 551, 553 [31 USPQ2d 1130] (Fed. Cir. 1994)

Accordingly, reconsideration of and withdrawal of the rejection of the claim is solicited.

For the sake of brevity, applicants herein repeat and incorporate by reference the prior remarks made with respect to Kitzke as being equally applicable to the current rejection in conjunction with Tuominen. As noted immediately above, Tuominen teaches a thickened AAC composition based on a specific thickening polymer. Kitzke teaches aerosol compositions which provides disinfection due to the presence of necessary "Quaternary" compounds. That such are essential constituents is seen from Kitzke who recites at col. 7:

(d) *Quaternary*.—Although a vast array of germicides are available commercially today including numerous quaternary compounds the compositions of the invention are limited to a specific class of quaternary compounds described in detail below. These compounds are unexpectedly well suited for use in the surface disinfecting-air sanitizing compositions of the invention by reason of their preeminent bactericidal properties. These quaternaries have been found to provide unobvious and unexpected surface disinfecting and air sanitizing performance when used in the compositions of the invention. 10 15

The need for the quaternary surfactants are reinforced by a review of the results reported on Kitzke's "Table 1" and "Table 3" each of which clearly identify the need for a pair of quaternary ammonium compounds needed to provide a disinfecting benefit to Kitzke's aerosol compositions. However, the additional consideration of Kitzke with Tuominen

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would not be technically feasible and would be considered inoperable as Tuominen's thickened AAC compositions would be recognized by a skilled artisan as being unsuitable for use in a pressurized, propellant containing composition which is an essential feature of Kitzke's compositions as such would be expected to clog any nozzle or dispenser due to the high viscosity of Tuominen's thickened AAC compositions. Such an inoperative combination would not render the applicant's presently claimed invention as being anticipated or being obvious and does not provide a suitable basis for maintaining the rejection of the claim. The Examiner is reminded that a reference may teach away from a use when that use would render the result inoperable. *McGinley v. Franklin Sports, Inc.*, 262 F.3d 1339, 1354 [60 USPQ2d 1001] (Fed. Cir. 2001). "A reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant." *In re Gurley*, 27 F.3d 551, 553 [31 USPQ2d 1130] (Fed. Cir. 1994)

Accordingly, reconsideration of and withdrawal of the rejection of the claim is solicited.

Early issuance of a *Notice of Allowability* is requested.

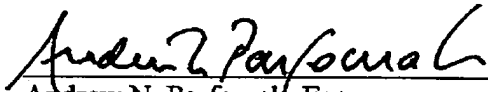
Should the Examiner believe that telephonic communication will advance the prosecution of the present application they are invited to telephone the undersigned at their convenience.

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CONDITIONAL AUTHORIZATION FOR FEES

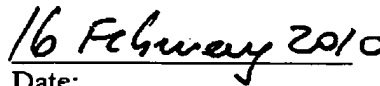
Should any further fee be required by the Commissioner in order to permit the timely entry of this paper, including any extension of time fees, the Commissioner is authorized to charge any such fee to Deposit Account No. 14-1263.

Respectfully Submitted;



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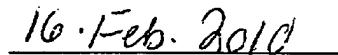
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